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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:

Applicant: Place, et al.

Application No.: 10/525,711

Date Filed: February 19, 2005

Title: DINOFLAGELLATE
KARLOTOXINS, METHODS
OF ISOLATION AND USES
THEREOF

Docket No.: 4115-184

Examiner: Ford, Allison M.

Art Unit: 1651

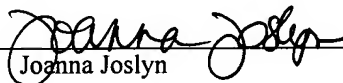
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FIRST CLASS MAIL CERTIFICATE

I hereby certify that I am mailing the attached documents to the Commissioner for Patents on the date specified, in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, and First Class Mailed under the provisions of 37 CFR 1.8.


Joanna Joslyn

September 29, 2005

INFORMATION DISCLOSURE STATEMENT

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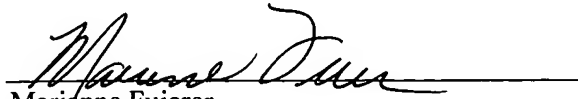
Sir:

Pursuant to 37 C.F.R. §1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO/SB/08A. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

- ☒ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No certification or fee is required.

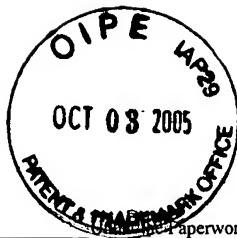
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(1).
- ☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(2).
- ☐ c. Attached is our check no. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. §1.17(p). Please credit or debit Deposit Account No. _____ as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Applicant(s) hereby petition(s) that the Information Disclosure Statement be considered. Attached is our check no. _____ in the amount of \$180.00 in payment of the petition fee under 37 C.F.R. §1.17(p). Please credit or debit Deposit Account No. _____ as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(1).
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Respectfully submitted,


Marianne Fuierer
Reg. No. 39,983
Attorney for Applicant

INTELLECTUAL PROPERTY/
TECHNOLOGY LAW
Telephone: (919) 419-9350
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Attorney Ref: 4115-184



PTO/SB/08A (01-04)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Sheet 1 of 9	COMPLETE IF KNOWN	
	Application Number	10/525,711
	Filing Date	February 18, 2005
	First Named Inventor	PLACE, et al.
	Art Unit	1651
	Examiner Name	Ford, Allison M.
	Attorney Docket Number	4115-184

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	Document Number	Publication Date MM-DD-YYYY	Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
	AA	US-5,011,672		04-30-1991	Garcia, D. Manuel
		US-			
		US-			
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¹ All the foreign patents and publications that are not written in English language are accompanied by their respective English abstracts, which constitute concise explanation of relevance of the non-English patents and publications that satisfy the requirements of 37 C.F.R. §1.98(a)(3)(i), according to MPEP 609 III A(3).

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NON-PATENT LITERATURE DOCUMENTS			
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	AB	Arzul, G., Gentien, P., Bodennec, G., Toularastel, F., Youenou, A., and Crassous, M. P., 1995. Comparison of toxic effects in <i>Gymnodinium cf. nagasakiense</i> polyunsaturated fatty acids In: Lassus, P., Arzul, G., Erard, E., Gentain, P. and Marcaillou, C. (Eds.), Harmful Marine Algal Blooms. Lavoisier, Intercept Ltd., pp. 395-400	
	AC	Arzul, G., Gentien, P., and Crassous, M., 1994. A haemolytic test to assay toxins excreted by the marine dinoflagellate <i>Gyrodinium cf. aureolum</i> . Water Res. 28(4), 961-965.	
	AD	ASTM, 1992. Standard guide for conducting toxicity tests with fishes, macroinvertebrates, and amphibians - E 729-88a. American Society for Testing and Materials, Philadelphia, pp. 403-422.	
	AE	Bodennec, G., Gentien, P., Parrish, C. C., Arzul, G., Youenou, A., and Crassous, M. P., 1995. Production of suspected lipid phycotoxins by <i>Gymnodinium cf. nagasakiense</i> in batch cultures. In: Lassus, P., Arzul, G., Erard, E., Gentain, P. and Marcaillou, C. (Eds.), Harmful Marine Algal Blooms. Lavoisier, Intercept Ltd., pp. 407-412.	
	AF	Botsford, L. W., Castilla, J. C., and Peterson, C. H., 1997. The management of fisheries and ecosystems. Science 227(5325), 509-515.	
	AG	Boyd, C. E., 1990. Water Quality in Ponds for Aquaculture. Birmingham Publishing Co., Birmingham, Alabama	
	AH	Braarud, T. 1957. A red water organism from Walvis Bay (<i>Gymnodinium galatheanum</i> n. sp.). Galathea Report. 1:137-138.	
	AI	Burkholder, J. M., and Glasgow, H. B., Jr., 1997. <i>Pfiesteria piscicida</i> and other <i>Pfiesteria</i> -like dinoflagellates: Behavior, impacts, and environmental controls. Limnol. Oceanogr. 42(5), 1052-1075	
	AJ	Burkholder, J.M., Glasgow, H.B., Deamer-Melia, N.J., Springer, J, Parrow, M.W., Zhang, C., Cancellieri, P.J., 2001. Species of the toxic <i>Pfiesteria</i> complex, and the importance of functional type in data interpretation. Environ. Health Perspec. (Supp.) 109(5), 667-679	

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	AK	Burkholder, J. M., Glasgow, H. B., Jr, Lewitus, A., Parrow, M., Zheng, C., Cancellieri, P., and Deamer-Melia, N., 2000. Functional type (toxicity status) controls Pfiesteria response to nutrients and algal prey versus fish prey. Symposium on Harmful Marine Algae in the U.S., Woods Hole, Massachusetts, pp. 24.	
	AL	Burkholder, J. M., Noga, E. J., Hobbs, C. W., Glasgow, H. B., Jr., and Smith, S. A., 1992. New "phantom" dinoflagellate is the causative agent of major estuarine fish kills. Nature 358, 407-410.	
	AM	Canadian Center for the Culture of Microorganisms (CCCM), Gymnodinium galatheanum, October 1998 http://www.botany.ubc.ca/cccm/NEPCC/NEPCC%20isolates/ndino/ndino807b.html accessed 1/21/05	
	AN	Daughbjerg, N., Hansen, G., Larsen, J., Moestrup, O., 2000. Phylogeny of some of the major genera of dinoflagellates based on ultrastructure and partial LSU rDNA sequence data, including the erection of three new genera of unarmoured dinoflagellates. Phycologia 39(4), 302-317.	
	AO	Deeds, J. R., Terlizzi, D. E., Stoecker, D. K., Way, R., and Place, A. R., 2000. Relationship between octadecapentaenoic acid, algicidal treatments, and toxicity in two bloom forming dinoflagellates, Karlodinium micrum and Prorocentrum minimum, found in the Chesapeake Bay, MD. Symposium on Harmful Marine Algae in the U.S., Woods Hole, Massachusetts, pp. 106.	
	AP	Deeds, J. R., Terlizzi, D. E., Adolf, J. E., Stoecker, D. K., and Place, A. R. (2002) Toxic activity from cultures of Karlodinium micrum (=Gyrodinium galatheanum) (Dinophyceae) - A dinoflagellate associated with fish mortalities in an estuarine aquaculture facility. Harmful Algae 1: 169-189.	
	AQ	D'Elia, C. F., Steudler, P. A., and Corwin, N. 1977. Determination and total nitrogen in aqueous samples using persulfate digestion. Limnol. Oceanogr. 22:760-764.	

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	AR	Edvardsen, B., Moy, F., and Paasche, E., 1990. Hemolytic activity in extracts of <i>Chrysochromulina polylepsis</i> grown at different levels of selenite and phosphate. In: Graneli, E. (Ed.), <i>Toxic Marine Phytoplankton</i> . Elsevier Science Publishing Co., Inc., Amsterdam, pp. 284-289	
	AS	Edvardsen, B., and Paasche, E., 1998. Bloom dynamics and physiology of <i>Prymnesium</i> and <i>Chrysochromulina</i> . In: Anderson, D.M., Cembella, A. D. and Hallegraeff, G. M. (Eds.), <i>Physiological Ecology of Harmful Algal Blooms</i> . Springer-Verlag, Berlin Heidelberg, pp. 193-208	
	AT	Fairey, E.R., Edmunds, J.S., Deamer-Melia, N.J., Glasgow, H., Jr., Johnson, F.M., Moeller, P.R., Burkholder, J.M., and Ramsdell, J.S., 1999. Reporter gene assay for fish-killing activity produced by <i>Pfiesteria piscicida</i> . <i>Environ. Health Perspect.</i> 170(9), 711-714.	
	AU	Fossat, B., Porthe-Nibelle, J., Sola, F., Masoni, A., Gentien, P., and Bodennec, G., 1999. Toxicity of fatty acid 18:5n3 from <i>Gymnodinium cf. mikimotoi</i> : II. Intracellular pH and K ⁺ uptake in isolated trout hepatocytes. <i>J. Appl. Toxicol.</i> 19, 275-278	
	AV	Glasgow, H. B. Jr., Burkholder, J. M., Mallin, M. A., Deamer-Melia, N. J., and Reed, R. E. 2001. Field ecology of toxic <i>Pfiesteria</i> complex species and a conservative analysis of their role in estuarine fish kills. <i>Env. Hlth. Persp. (suppl. 5)</i> 109:715-730	
	AW	Glibert, P. M. and Terlizzi, D. E. 1999. Cooccurrence of elevated urea levels and dinoflagellate blooms in temperate estuarine aquaculture ponds. <i>Appl. Environ. Microbiol.</i> 65 (12): 5594-5596.	
	AX	Glibert, P. M., Magnien, R., Lomas, M. W., Alexander, J., Fan, C., Haramoto, E., Trice, M., and Kana, T. M. 2001. Harmful algal blooms in the Chesapeake and coastal bays of Maryland, USA: Comparison of 1997, 1998, and 1999 events. <i>Estuaries</i> 24:875-883. ABSTRACT ONLY	
	AY	Guo, M., Harrison, P. J., and Taylor, F. J. R., 1996. Fish kills related to <i>Prymnesium parvum</i> N. Carter (Haptophyta) in the People's Republic of China. <i>J. Appl. Phycol.</i> 8, 111-117.	
	AZ	Hallegraeff, G. M., 1993. A review of harmful algal blooms and their apparent global increase. <i>Phycologia</i> 32(2), 79-99.	

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	BA	Intergovernmental Oceanographic Commission, "Karlodinium micrum," January 2004 (01.2004), http://bi.ku.db/ioc/details.asp?Algae_ID=74 accessed 1/21/05	
	BB	Johansson, N., and Graneli, E., 1999. Cell density, chemical composition and toxicity of <i>Chrysochromulina polylepis</i> (Haptophyta) in relation to different N:P supply ratios. <i>Mar. Biol.</i> 135, 209-217.	
	BC	Jones, K. J., Ayres, P., Bullock, A. M., Roberts, R. J., and Tett, P., 1982. A red tide of <i>Gyrodinium aureolum</i> in sea lochs of the Firth of Clyde and associated mortality of pondreared salmon. <i>J. Mar. Biol. Assoc. U.K.</i> 62, 771-782.	
	BD	Kempton, J. W., Lewitus, A. J., Deeds, J. R., Law, J. M. & Place, A. R. Toxicity of <i>Karlodinium micrum</i> (Dinophyceae) associated with a fish kill in a South Carolina brackish retention pond. <i>Harmful Algae</i> 1, 233-241 (2002)	
	BE	Khan, S., Arakawa, O., and Onoue, Y., 1997. Neurotoxins in a toxic red tide of <i>Heterosigma akashiwo</i> (Raphidophyceae) in Kagoshima Bay, Japan. <i>Aquac. Res.</i> 28, 9-14	
	BF	Kite, G.C., and Dodge, J.D., 1988. Cell and Chloroplast Ultrastructure in <i>Gyrodinium aureolum</i> and <i>Gymnodinium galatheanum</i> . Two marine Dinoflagellates containing an unusual carotenoid <i>Sarsia</i> 73: 131-138. Bergen.	
	BG	Lewitus, A. J., Burkholder, J. M., Glasgow Jr., H. B., Glibert, P. M., Willis, B. M., Hayes, K. C. and Burke, M. K. 1999. Mixotrophy and nutrient uptake by <i>Pfiesteria piscicida</i> (Dinophyceae). <i>J. Phycol.</i> 35:1430-1437	
	BH	Lewitus, A. J. and Holland, A. F. 2002. Initial results from a multi-institutional collaboration to monitor harmful algal blooms in South Carolina. In: <i>Proceedings of the EMAP Symposium 2001: Coastal Monitoring Through Partnership; Environmental Monitoring and Assessment</i> (special issue), pp. 365-375	

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	BI	Lewitus, A.J., Hayes, K. C., Willis, B. M., Burkholder, J. M., Glasgow, Jr. H. B., Holland, A. F., Maier, P., Rublee, P. A., and Magnien, R. 2002. Low abundance of the dinoflagellates, <i>Pfiesteria piscicida</i> , <i>P. shumwayae</i> , and <i>Cryptoperidiniopsis</i> spp. in South Carolina estuaries: Relevance as reference sites to areas impacted by <i>Pfiesteria</i> toxic events. <i>Estuaries</i> 25	
	BJ	Li, A., Stoecker, D. K., Coats, D. W., and Adams, E. J. 1996. Ingestion of fluorescently-labeled and phycoerythrin-containing prey by photosynthetic dinoflagellates. <i>Aquat. Microb. Ecol.</i> 10:139-147. ABSTRACT ONLY	
	BK	Li, A., Stoecker, D. K., and Adolf, J. E., 1999. Feeding, pigmentation, photosynthesis and growth of the mixotrophic dinoflagellate <i>Karlodinium micrum</i> . <i>Aquat. Microb. Ecol.</i> 19, 163-176	
	BL	Li, A., Stoecker, D. K., and Coats, D. W. 2000. Mixotrophy in <i>Gyrodinium galatheanum</i> (Dinophyceae): grazing responses to light intensity and inorganic nutrients. <i>J. Phycol.</i> 36:33-45.	
	BM	Li, A., Stoecker, D. K., and Coats, D. W., 2000. Spatial and temporal aspects of <i>Gyrodinium galatheanum</i> in Chesapeake Bay: distribution and mixotrophy. <i>J. Plankton. Res.</i> 22(11), 2105-2124	
	BN	Marshall, H. G., 1999. <i>Pfiesteria piscicida</i> and dinoflagellates similar to <i>Pfiesteria</i> . <i>VA. J. Science</i> 50(4), 281-285	
	BO	Masser, M. P., 2000. Aquatic vegetation control. In: R. R. Stickney (Ed.), <i>Encyclopedia of Aquaculture</i> . John Wiley and Sons Inc., New York, pp. 51-61.	
	BP	Millie D. F., Kirkpatrick, G. J., and Vinyard, B. T. 1995. Relating photosynthetic pigments in vivo optical density spectra to irradiance for the Florida red-tide dinoflagellate <i>Gymnodinium breve</i> . <i>Mar. Ecol. Prog. Ser.</i> 120:65-75. ABSTRACT ONLY	
	BQ	Nielsen, M.V. 1993. Toxic effect of the marine dinoflagellate <i>Gymnodinium galatheanum</i> on juvenile cod <i>Gadus morhua</i> . <i>Mar. Ecol. Prog. Ser.</i> 95:273-277	
	BR	Nielsen, M. V. 1996. Chemical composition of the toxic dinoflagellate <i>Gymnodinium galatheanum</i> in relation to irradiance, temperature and salinity. <i>Mar. Ecol. Prog. Ser.</i> 136:205-211	

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	BS	Nielsen, M. V. and Stromgren, T. 1991. Shell growth response of mussels (<i>Mytilus edulis</i>) exposed to toxic microalgae. <i>Mar. Biol.</i> 108:263-267	
	BT	Parrish, C. C., Bodennec, G., and Gentien, P., 1998. Haemolytic glycolipids from <i>Gymnodinium</i> species. <i>Phytochemistry</i> 47(5), 783-787	
	BU	Pieterse, F. and Van Der Post, D. C., 1967. The Pilchard of South West Africa (<i>Sardinops ocellata</i>) Oceanographic conditions associated with red-tides and fish mortalities in the Walvis Bay region. <i>Investigational Report No. 14</i> , 8-27	
	BV	Reardon, I. S., and Harrell, R. M., 1990. Acute toxicity of formalin and copper sulfate to striped bass fingerlings held in varying salinities. <i>Aquaculture</i> 87, 255-270	
	BW	Roberts, R. J., Bullock, A. M., Turner, M., Jones, K., and Tett, P., 1983. Mortalities of <i>Salmo gairdneri</i> exposed to cultures of <i>Gyrodinium aureolum</i> . <i>J. Mar. Biol. Assoc. U.K.</i> 63, 741-743.	
	BX	Smayda, T. J. 1997. Harmful algal blooms: their ecophysiology and general relevance to phytoplankton blooms in the sea. <i>Limnol. Oceanogr.</i> 42:1137-1153	
	BY	Smayda, T. J. 1998. Ecophysiology and bloom dynamics of <i>Heterosigma akashiwo</i> (Raphidophyceae). In: Anderson, D. M., Cembella, A. D., and Hallegraeff, G. M. (Eds.) <i>Physiological Ecology of Harmful Algal Blooms</i> . Springer-Verlag, Berlin, pp. 113-131	
	BZ	Sola, F., Masoni, A., Fossat, B., Porthe-Nibelle, J., Gentien, P., and Bodennec, G., 1999. Toxicity of fatty acid 18:5n3 from <i>Gymnodinium cf. mikimotoi</i> : I. Morphological and biochemical aspects on <i>Dicentrarchus labrax</i> gills and intestines. <i>J. Appl. Toxicol.</i> 19, 279-284.	
	CA	Steidinger, K. A., Burkholder, J. M., Glasgow, H. B. J., Hobbs, C. W., Garrett, J. K., Truby, E. W., Noga, E. J., and Smith, S. A., 1996. <i>Pfiesteria piscicida</i> gen. et sp. nov. (Pfiesteriaceae fam. nov.), A new toxic dinoflagellate with a complex life cycle and behavior. <i>J. Phycol.</i> 32, 157-164	

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<p align="center">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p align="center">Sheet 8 of 9</p>	<i>COMPLETE IF KNOWN</i>	
	Application Number	10/525,711
	Filing Date	February 18, 2005
	First Named Inventor	PLACE, et al.
	Art Unit	1651
	Examiner Name	Ford, Allison M.
	Attorney Docket Number	4115-184

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume/issue number(s), publisher, city and/or country where published	T ²
	CB	Tengs, T., Bowers, H. A., Ziman, A. P., Stoecker, D. K., and Oldach, D. W. 2001. Genetic polymorphism in <i>Gymnodinium galatheanum</i> chloroplast DNA sequences and development of a molecular detection assay. <i>Mol. Ecol.</i> 10(2):515-523	
	CC	Terlizzi, D. E., Stoecker, D. K., Glibert, P. M. 2000. <i>Gyrodinium galatheanum</i> : a threat to estuarine aquaculture waters. In: <i>Responsible Aquaculture in the New Millenium. Abstracts of Contributions Presented at the International Conference AQUA 2000, Nice, France, May 2-6, 2000</i> (Eds. Flos R, Cressell L), European Aquaculture Society Special Publication 28, Ostende, Belgium. pp. 700	
	CD	Tucker, C. S., 1987. Acute toxicity of potassium permanganate to channel catfish fingerlings. <i>Aquaculture</i> 60, 93-98.	
	CE	Tucker, C. S., 1989. Method for estimating potassium permanganate disease treatment rates for channel catfish in ponds. <i>Prog. Fish. Cult.</i> 51, 24-26	
	CF	Tucker, C. S., and Boyd, C. E., 1977. Relationships between potassium permanganate treatment and water quality. <i>T. Am. Fish. Soc.</i> 106(5), 481-488	
	CG	Ulitzer, S., and Shilo, M., 1966. Mode of action of <i>Prymnesium parvum</i> ichthyotoxin. <i>J. Protozool.</i> 13(2), 332-336.	
	CH	Ulitzer, S., and Shilo, M., 1970. Procedure for purification and separation of <i>Prymnesium parvum</i> toxins. <i>Biochim. Biophys. Acta</i> 201, 350-363	
	CI	Xi, D., Kurtz, D.T., and Ramsdell, J.S., 1996. Maitotoxin-elevated cytosolic free calcium in GH4C1 rat pituitary cells nimodipine-sensitive and -insensitive mechanisms. <i>Biochem. Pharmacol.</i> 51(6) 759-769	

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	CJ	Yasumoto, T., Underdal, B., Aune, T., Hormazabal, V., Skulberg, O. M., and Oshima, Y., 1990. Screening for hemolytic and ichthyotoxic components of <i>Chrysochromulina polylepis</i> and <i>Gyrodinium aureolum</i> from Norwegian coastal waters. In: Granell, E., (Ed.), Toxic Marine Phytoplankton. Elsevier Science Publishing Co., Inc., Amsterdam, pp. 436-440	
	CK	Yongmanitchai, W. & Ward, O. P. Separation of lipid classes from <i>Phaeodactylum tricornutum</i> using silica cartridges. <i>Phytochemistry</i> 31 , 3405-3408 (1992)	
	CL	Young, R.C., McLaren, M., and Ramsdell, J.S., 1995. Maitotoxin increases voltage independent chloride and sodium currents in GH4C1 rat pituitary cells. <i>Nat. Toxins</i> 3 (6), 419-427	

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